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(54) Title: ADJUVANT COMBINATION FORMULATIONS

(57) Abstract: The use of an aminoalkyl glucosamine phosphate compound, or a derivative or analog thereof, in combination with a cytokine or lymphokine such as granulocyte macrophage colony stimulating factor or interleukin-12, is useful as an adjuvant combination in an antigenic composition to enhance the immune response in a vertebrate host to a selected antigen.



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INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K39/39 A61P31/00 A61P31/18 A61P35/00 A61P37/00
 A61P25/18 //A61K39/21, A61K39/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WO 98 50399 A (RIBI IMMUNOCHEM RESEARCH INC) 12 November 1998 (1998-11-12)</p> <p>abstract page 2, line 18 - line 27 page 4, line 27 -page 5, line 28 page 6, line 7 - line 8 example 20 page 76, line 22 -page 88, line 25 page 106, line 5 -page 113</p> <p style="text-align: center;">--- -/--</p>	<p>1-13, 20-32, 39-42, 49-51, 56, 61-66</p>

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

In International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WO 00 60084 A (SMITHKLINE BEECHAM BIOLOG ;VINALS Y DE BASSOLS CARLOTA (BE); CORIX) 12 October 2000 (2000-10-12)</p> <p>page 22, line 6 -page 23, line 7 page 25, line 7 - line 19 page 26, line 19 - line 27 claims 25,26</p> <p>---</p>	<p>1-13, 20-32, 39-42, 49-51, 56,61-66</p>
Y	<p>US 5 980 911 A (CORNER LEIGH AUSTIN ET AL) 9 November 1999 (1999-11-09)</p> <p>the whole document</p> <p>---</p>	<p>1-13, 20-32, 39-42, 49-51, 56,61-66</p>
Y	<p>US 5 679 356 A (BONNEM ERIC M ET AL) 21 October 1997 (1997-10-21) cited in the application</p> <p>the whole document</p> <p>---</p>	<p>1-13, 20-32, 39-42, 49-51, 56,61-66</p>
Y	<p>WO 98 57659 A (SMITHKLINE BEECHAM BIOLOG ;BOON THIERRY (BE); SILLA SILVIA (BE); U) 23 December 1998 (1998-12-23)</p> <p>the whole document</p> <p>---</p>	<p>1-13, 20-32, 39-42, 49-51, 56,61-66</p>
A	<p>HAYNES B F ET AL: "HIV type 1 V3 region primer-induced antibody suppression is overcome by administration of C4-V3 peptides as a polyvalent immunogen." AIDS RESEARCH AND HUMAN RETROVIRUSES. UNITED STATES FEB 1995, vol. 11, no. 2, February 1995 (1995-02), pages 211-221, XP001108967 ISSN: 0889-2229 cited in the application abstract table 1</p> <p>---</p> <p>--- -/--</p>	<p>14-16, 33-35, 43-45</p>

INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>KURODA MARCELO J ET AL: "Analysis of Gag-specific cytotoxic T lymphocytes in simian immunodeficiency virus-infected rhesus monkeys by cell staining with a tetrameric major histocompatibility complex class I-peptide complex." JOURNAL OF EXPERIMENTAL MEDICINE, vol. 187, no. 9, 4 May 1998 (1998-05-04), pages 1373-1381, XP002214739 ISSN: 0022-1007 cited in the application abstract column 2, paragraph 3</p>	14,17, 33,36, 43,46
A	<p>LIAO HUA-XIN ET AL: "Induction of antibodies in guinea pigs and rhesus monkeys against the human immunodeficiency virus type 1 envelope: Neutralization of nonpathogenic and pathogenic primary isolate simian/human immunodeficiency virus strains." JOURNAL OF VIROLOGY, vol. 74, no. 1, January 2000 (2000-01), pages 254-263, XP002214740 ISSN: 0022-538X cited in the application abstract page 255, column 2, paragraph 1</p>	14,18, 19,33, 37,38, 43,47,48
A	<p>WO 99 27944 A (SCHENK DALE B ;ATHENA NEUROSCIENCES INC (US)) 10 June 1999 (1999-06-10) cited in the application abstract page 3, line 18 - line 28 page 14, line 30 - line 34</p>	52-55, 57-60

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/46943**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 29-50, 56-60 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9850399	A	12-11-1998	US 6113918 A	05-09-2000
			AU 740663 B2	08-11-2001
			AU 7474798 A	27-11-1998
			BR 9809791 A	27-06-2000
			CN 1265112 T	30-08-2000
			EP 0983286 A1	08-03-2000
			HU 0004147 A2	28-04-2001
			JP 2002512623 T	23-04-2002
			NZ 500938 A	31-05-2002
			PL 343205 A1	30-07-2001
			US 6355257 B1	12-03-2002
			WO 9850399 A1	12-11-1998
			US 6303347 B1	16-10-2001
			US 2002048588 A1	25-04-2002
WO 0060084	A	12-10-2000	AU 4452900 A	23-10-2000
			EP 1169450 A1	09-01-2002
			WO 0060084 A1	12-10-2000
US 5980911	A	09-11-1999	AU 694774 B2	30-07-1998
			AU 2341195 A	29-11-1995
			WO 9530436 A1	16-11-1995
			CA 2189432 A1	16-11-1995
			EP 0755266 A1	29-01-1997
			NZ 284778 A	27-05-1998
US 5679356	A	21-10-1997	AU 4662393 A	31-01-1994
			CN 1091978 A	14-09-1994
			EP 0651656 A1	10-05-1995
			JP 7504683 T	25-05-1995
			MX 9304089 A1	31-01-1994
			WO 9401133 A1	20-01-1994
			ZA 9304890 A	14-04-1994
WO 9857659	A	23-12-1998	WO 9857659 A1	23-12-1998
			WO 9857660 A1	23-12-1998
			EP 1001808 A1	24-05-2000
			EP 0977589 A1	09-02-2000
			JP 2002504135 T	05-02-2002
			JP 2002504136 T	05-02-2002
			US 6375945 B1	23-04-2002
WO 9927944	A	10-06-1999	BG 104562 A	31-01-2001
			BR 9815357 A	24-10-2000
			CA 2312920 A1	10-06-1999
			CN 1281366 T	24-01-2001
			DE 1033996 T1	07-06-2001
			EE 200000379 A	16-04-2001
			EP 1033996 A1	13-09-2000
			HR 20000443 A1	31-10-2000
			HU 0100627 A2	28-06-2001
			JP 2002502802 T	29-01-2002
			NO 20002784 A	31-07-2000
			PL 342649 A1	18-06-2001
			TR 200001608 T2	23-07-2001
			WO 9927944 A1	10-06-1999
			AU 1706199 A	16-06-1999
			ZA 9810932 A	02-07-1999